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6, 1958, by the Food Drug and Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) *Food* includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 55206, Oct. 14, 1977]

§ 570.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquirers as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929, Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health".

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or

(2) Is generally recognized as safe (GRAS); or

(3) Has prior sanction or approval under that amendment; or

(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in

which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance (HFV-200), 7500 Standish Pl., Rockville, MD 20855, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in regulations in this Subchapter E if the articles are used in accordance with the requirements of such regulations.

[41 FR 38644, Sept. 10, 1976, as amended at 54 FR 18281, Apr. 28, 1989; 57 FR 6476, Feb. 25, 1992]

§ 570.13 Indirect food additives resulting from packaging materials prior sanctioned for animal feed and pet food.

Regulations providing for the use of food packaging materials as prior sanctioned in part 181 of this chapter are incorporated in Subchapter E as applicable to packaging materials used for animal feed and pet food.

[42 FR 14091, Mar. 15, 1977]

§ 570.14 Indirect food additives resulting from packaging materials for animal feed and pet food.

Regulations providing for the use of food packaging materials in parts 174 through 179 of this chapter are incorporated in Subchapter E as applicable

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to packaging materials used for animal feed and pet food.

[42 FR 14091, Mar. 15, 1977]

§ 570.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall proceed as provided in part 10 of this chapter.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977]

§ 570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with § 511.1 of this chapter or by the Department of Agriculture in accordance with 9 CFR 309.17, and it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in part 58 of this chapter.

[41 FR 38644, Sept. 10, 1976, as amended at 43 FR 60023, Dec. 22, 1978]

§ 570.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.